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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/525,878

09/27/2005

Kenji Yasuda

2005-0296A

4129

513

7590

03/30/2010

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EXAMINER

HOBBS, MICHAEL L

ART UNIT

PAPER NUMBER

1797

NOTIFICATION DATE

DELIVERY MODE

03/30/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/525,878	<b>Applicant(s)</b> YASUDA, KENJI	
	<b>Examiner</b> MICHAEL HOBBS	<b>Art Unit</b> 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 04 March 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 6-11 and 13-25 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 6-11 and 13-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 February 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)         | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 02/04/2010 has been entered.
2. Claims 6-11 and 13-25 are pending further examination upon the merits.

### ***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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5. Claims 6, 7, 9, 11 and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Xing et al. (CN 1427255A) (closest English language translation is US 2005/0106708 A1) in view of Yasuda et al. (US 7,092,154 B1) (will be referred to as Yasuda) and in further view of Xu et al. (US 2005/0112544 A1) (claims priority back to US Provisional Application 60/435,400 filed on 12/20/2002).

The applied reference, Yasuda, has a common inventor and assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(I)(1) and § 706.02(I)(2).

6. Xing discloses an apparatus for stimulating an animal cell such as a nerve cell ([0036]) that includes for claim 1 a chamber (chamber 5) or micro-chamber) that includes an electrode array (array 2; [0033]) where each electrode is surrounded by a

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insulating layer (layer 1) that forms a wall around each electrode site (Fig. 1; [0032]).

The electrode sites or regions connected by trenches ([0032]), which allow the neural cells on each site to form a neural network ([0036]). However, Xing is silent regarding an optically transparent membrane over the regions.

7. Yasuda discloses an apparatus for microscopic observation of long-term cultures that includes the cells being formed onto a substrate covered with a semi-permeable membrane. For claim 6, Yasuda discloses that the membrane used to cover the cells is an optically transparent membrane (col. 2 lines 57-58) and the membrane is coarse enough to prevent cells from passing through the membrane (col. 2 lines 58-59). Therefore, it would be obvious to one of ordinary skill in the art to employ the membrane as suggested by Yasuda in order to retain the cells within the wells of Xing. The suggestion for doing so at the time would have been in order to prevent the cells from coming out of the hole or well (col. 2 lines 59-61).

8. Xing and Yasuda differ from the instant application regarding the electrodes being coated with either laminin or collagen.

9. Xu discloses an impedance based device used for assays that for claim 6 discloses electrodes that are coated with either laminin or collagen ([0164]). This coating provides the advantage of promoting cell attachment on to the electrode surface ([0161]). Therefore, it would have been obvious for one of ordinary skill in the art to employ the conventional coating of Xu over the electrodes of Xing and Yasuda with a reasonable expectation of success. The suggestion for doing so at the time would have

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been in order to have a surface that promotes specific cell attachment to the electrode array surface ([0184]).

10. Regarding claim 7, Xing discloses using an electrode to record a physiological signal from the substrate ([0005]) and is therefore fully capable of measuring the potential change of a nerve cell at the same electrode. See also MPEP 2115 for material worked upon by an apparatus.

11. For claims 9, 11 and 16, Xing discloses an electrode array where the electrodes are fully capable of operating independently.

12. Applicant cannot rely upon the foreign priority papers to overcome this rejection because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

13. Claims 6-9, 11 and 15-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jimbo et al. (IEEE Transactions on Biomedical Engineering. Vol. 40 no. 8 August 1993) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni).

14. Jumbo discloses a substrate for multi-site monitoring of electrical signals using multi-electrode array for monitoring the growth of neural cells. For claim 6, Jimbo discloses a substrate with an electrode array for monitoring electrical signals or measuring potential from neurites (section II Experimental Method, sub-section A *Fabrication of Electrode Array Substrates*). The substrates are constructed from a glass substrate with ITO (indium tin oxide) electrodes and with wells formed of a double layer

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of  $\text{Al}_2\text{O}_3$  and polyimide (section II Experimental Method, sub-section A *Fabrication of Electrode Array Substrates*). The wells form a wall around each measuring site and these walls are "discontinuous" since each site is connected by a conduit (Fig. 2).

Finally, Jimbo discloses placing a coating of poly-L-lysine and laminin (section II Experimental Method, sub-section B *Cell Culture* lines 1-6 of the first paragraph) in order to promote cell adhesion.

15. However, Jimbo is silent regarding an optically transparent membrane over the regions.

16. Hänni discloses a device for organic cell culture for testing the electrophysiological activity of nerve cells. For claim 6, Hänni discloses that a transparent porous membrane (membrane 16) is placed on the support structure (support 11) in order to cover an opening (opening 15; col. 3 lines 9-11). Therefore, it would be obvious to one of ordinary skill in the art to employ the membrane as suggested by Hänni in order to retain the cells within the wells of Jimbo. The suggestion for doing so at the time would have been in order to provide a cover for the opening (col. 3 lines 11-12).

17. For claim 7, Jimbo discloses an electrode array as discussed above that is fully capable of measuring the potential change of a nerve cell on the same electrode and for claims 8,15, the electrodes are made of ITO which is a transparent conductive material (section II Experimental Method, sub-section A *Fabrication of Electrode Array Substrates*). For claims 9 and 16-18, Jimbo further discloses at least three electrodes

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within the array that are fully capable of carrying out measurements independently and for claim 11 the number of regions is at least three or greater as shown in Figure 3.

18. Claims 13 and 19-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jimbo et al. (IEEE Transactions on Biomedical Engineering. Vol. 40 no. 8 August 1993) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni) as applied above and in further view of Sugihara et al. (WO 99/34202) (will be referred to as Sugihara).

19. For claim 13, Jimbo discloses attaching the substrate to a 16 channel amplifier and observing the cells by way of an SIT camera (Fig. 4; section II Experimental Method, sub-section C *Measurement System*), but both Jimbo and Hänni are silent about mounting the substrate on a microscope slide.

20. For claim 13, Sugihara discloses attaching the substrate containing the electrode arrays to a holder (holder 3 & 4; page 11 lines 22-23) where the electrical contacts for the microelectrodes (electrode 34) are attached to an amplifier (amplifier 24; page 13 lines 21 and 22). The cells are observed by an inverted microscope (microscope 21) that optically measures the cells and a computer is used for processing the output signal from the cells on the holder (page 6 lines 26-29). Therefore, it would be obvious for one of ordinary skill in the art to employ the microscope mounting slide and microscope as suggested by Sugihara within Jimbo and Hänni in order to obtain the predictable result of monitoring the neural cells.



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21. For claims 19-25, Jimbo and Hänni are silent about the walls being made of a photo-curable resin.

22. With regards to claims 10 and 19-25, Sugihara further discloses that the electrode sites or compartments are formed by applying the ITO film to a glass substrate and the conductive pattern is formed by photo-resist and etching (page 10 lines 15-16). The insulating film is formed by a negative photosensitive polyimide film or photo-curable resin (page 10 lines 16-17). Furthermore, Sugihara demonstrates that using a photo-curable material to form a culture chamber for cells was known at the time of the instant application. Therefore, following rationale C of *KSR*, 550 U.S. at \_\_\_\_, 82 USPQ2d at 1396, it would have been obvious to one of ordinary skill in the art to employ the photo-curable resin suggested by Sugihara within the culture chamber of Klemic and Hänni in order to construct the well walls with predictable results.

23. Applicant is reminded that process steps in an apparatus are not accorded patentable weight. "The patentability of a product does not depend on its method of production". If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process (*In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)). Furthermore, the processing steps do not structurally define the instant application over the prior art since the claimed processing steps do not impart a distinctive structural characteristic to the final product.

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24. Claim 14 is rejected under 35 U.S.C. 103(a) as being unpatentable over Jimbo et al. (IEEE Transactions on Biomedical Engineering. Vol. 40 no. 8 August 1993) in view of Hänni et al. (US 6,689,594 B1) (will be referred to as Hänni) as applied above and in further views of Sugihara et al. (WO 99/34202) (will be referred to as Sugihara) and Varalli et al. (US 2001/0041830 A1) (will be referred to as Varalli).

25. Jimbo, Hänni and Sugihara are silent regarding the amplifier and computer being optically connected.

26. Varalli discloses an apparatus for measuring the content of glucose, lactate and other metabolites in biological fluids. Varalli also includes a measurement instrument that is connected to a patient and that transmits the data from the measuring device back to a computer. For claim 14, Varalli discloses that the connection between the measurement instrument and an external computer is an IR optical transmission system ([0037]). Other optical transmission systems that are known and used, for example, for connections between computers and peripheral units (for example, between the HP-42S and a printer) include protocols such as IRLAP (from the Infrared Data Association) and the Infrared Physical Layer Link which is used on some HP components ([0038]). Therefore, it would be obvious to one of ordinary skill in the art to employ the optical connections suggested by Varalli in order to connect the electrode array of Jimbo, Hänni and Sugihara with a computer. The suggestion for doing so at the time would have been in order to guarantee the total electrical isolation of the electrical circuits for the measurement system ([0037]).

***Response to Arguments***

27. Applicant's arguments filed 03/04/2010 have been fully considered but they are not persuasive. Applicant argues in the last paragraph of page 5 that none of the cited references disclose covering the electrodes with a layer of laminin or collagen. With regards to the applied references of Xing and Yasuda, this deficiency within the reference is corrected by the newly applied reference of Xu which discloses a layer of laminin or collagen as a cell adhesion surface.

28. Regarding the applied reference of Jimbo, the examiner respectfully disagrees with the characterization of the reference as the applied reference discloses forming a cell adhesion surface on the top of the electrodes as was discussed above.

***Conclusion***

29. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL HOBBS whose telephone number is (571)270-3724. The examiner can normally be reached on Monday-Thursday 7:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Marcheschi can be reached on (571) 272-1374. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/William H. Beisner/  
Primary Examiner, Art Unit 1797

/M. H./  
Examiner, Art Unit 1797